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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/877,150 06/17/97 ULLRICH

A 225/298

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HM22/0517

EXAMINER

MURPHY, J

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED:

05/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/877,150

Applicant(s)

ULLRICH ET AL.

Examiner

Joseph F Murphy

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8, 18-20, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 4 and 8 is/are allowed. *Appl*
- 6) ☒ Claim(s) 2, 5, 18, 28 and 29 is/are rejected.
- 7) ☒ Claim(s) 6, 19 and 20 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
- ☐ received.
 - ☐ received in Application No. (Series Code / Serial Number) _____.
 - ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____

Art Unit: 1644

DETAILED ACTION

Claims 1 and 7 were cancelled, claims 3-6, 8, 18-20 were amended in Paper No. 15, 11/1/1999 (Entered in Part).

New claims 28 and 29 were added in Paper No. 18, 3/28/2000.

Claims 2-6, 8, 18-20 and 28-29 are under consideration.

The rejection of claims 4-6 under 35 USC § 101 has been obviated by Applicant's amendment in Paper No. 15, 11/1/1999, and is thus withdrawn.

The cancellation of claim 7 in Paper No. 15, 11/1/1999 has rendered moot the rejection under 35 USC § 112, second paragraph.

The objection under 37 CFR § 1.75(c) of claim 3 has been obviated by Applicant's amendment in Paper No. 15, 11/1/1999 and is thus withdrawn.

The rejection of claims 2, 4-6, 18-20 under 35 USC § 102 has been obviated by Applicant's amendment in Paper No. 15, 11/1/1999, and is thus withdrawn. The cancellation of claims 1 and 7 in Paper No. 15, 11/1/1999 has rendered moot the rejection under 35 USC § 102.

Claim Objections

Claims 6 and 19-20 are objected to because of the following informalities: These claims are dependent on canceled claims 21 and 22. Appropriate correction is required.

Art Unit: 1644

Claim Rejections - 35 USC § 112 first paragraph

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses a nucleic acid sequence encoding BDP-1 having the amino acid sequence shown in SEQ ID NO. 36. This nucleic acid encoding SEQ ID No. 36 meets the written description and enablement provisions of 35 U.S.C. 112, first paragraph. However, the claims are directed to encompass a nucleic acid molecules isolated from mammals that encode BDP-1 having undisclosed amino acid sequence which correspond to sequences from other species. None of the these nucleic acid molecules encoding a BDP-1 meet the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. V. Makurhar, 19 USPQ2d 1111, makes clear that applicant must convey with reasonable clarity to those skilled in the art, as the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry whatever is now claimed (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath Inc. V. Makurhar, page 1116.).

With the exception of a polynucleotide encoding SEQ ID No. 36 the skilled artisan can not envision the detailed chemical structure of the encompassed polynucleotides and therefore

Art Unit: 1644

conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that is part of the invention and reference to a potential method for isolating it, The nucleic acid itself is required,. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.* 18 USPQ 2d 1016.

One can not describe what one has not conceived. See *Fiddes v. Baird* 30 USPQ 2d 1481, 1483.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell in culture comprising a polynucleotide with the sequence as set forth in SEQ ID NO: 36, does not reasonably provide enablement for in vivo transfection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification on page 19, line 35 discloses that the invention features recombinant nucleic acid, preferably in a cell or an organism. However, there are no actual or prophetic examples that disclose how to make or use host cells that comprise a polynucleotide sequence as set forth in SEQ ID NO: 36 in an animal. As is commonly known in the art, the transfection of cells within an animal with foreign nucleotide sequences is fraught with difficulty, and is complicated by many variables, including among others, the method of delivery of the

Art Unit: 1644

polynucleotide, the appropriate vector which comprises the polynucleotide of interest, and continued expression of the polynucleotide within the host cells. The instant disclosure does not address any of the methods necessary to make a host cell in an animal which comprises the polynucleotide of interest, therefore, the claims as written are not enabled.

Claim Rejections - 35 USC § 112 second paragraph

Claims 18, 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is vague and indefinite in the recitation of "as one of the following", because there is only one condition enumerated.

Claims 28-29 are vague and indefinite in the recitation of the term "lacking one or more, but not all". The metes and bounds of this claim are unclear.

Conclusion

Claims 3-4 and 8 are allowable.

Claims 2, 5, 18 and 28-29 are rejected.

Claims 6 and 19-20 are objected to.


Advisory Information

Art Unit: 1644


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1644
May 15, 2000



PREMA MERTZ
PRIMARY EXAMINER